

## **LABELLING**

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

### **HDPE bottle**

#### **1. Name of the medicinal product**

[HA779 trade name]\* Abacavir (as sulfate)/ dolutegravir (as sodium)/ lamivudine 60 mg/5 mg/30 mg film-coated dispersible tablets

Abacavir (as sulfate)/ dolutegravir (as sodium)/ lamivudine

#### **2. Statement of active substance**

Each tablet contains 60 mg abacavir (as sulfate), 5 mg dolutegravir (as sodium) and 30 mg lamivudine

#### **3. List of excipients**

Each tablet contains aspartame.

See the patient information leaflet for further information.

#### **4. Pharmaceutical form and contents**

Dispersible tablets

30 tablets

90 tablets

#### **5. Method and route of administration**

Oral use.

Read the patient information leaflet before use.

#### **6. Special warning that the medicinal product must be stored out of the reach and sight of children**

Keep this medicine out of the reach and sight of children.

#### **7. Other special warning(s), if necessary**

#### **8. Expiry date**

EXP {MM/YYYY}

#### **9. Special storage conditions**

Do not store above 30°C. Store in the original container.

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\* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

**10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate**

**11. Name and address of the supplier**

Cipla Limited  
Cipla House, Peninsula Business Park,  
Ganpatrao, Kadam Marg, Lower Parel,  
Mumbai, Maharashtra 400013,  
India

**12. WHO Reference Number (Prequalification Programme)**

HA779

**13. Manufacturer's batch number**

<Batch> <Lot> {number}

**14. (Advice on) General classification for supply**

Medicinal product subject to medical prescription.

**15. Instructions on use**